

REMARKS

I. Background

The present Amendment is in response to the Examiner's Office Action mailed October 26, 2006. At the time of the Office Action, claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75, 77 and 78 were pending in the application. By this amendment, claims 11, 21, 27, 32, 40, 47, 50, 63, 68 and 73 have been amended, claims 77 and 78 have been cancelled, and new claims 80-90 have been added. Accordingly, claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75, and 80-90 remain pending for consideration.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

II. Proposed Amendments

The specification was amended to correct an element numbering discrepancy. Claims 11, 21, 27, 32, 40, 47, 50, 63, 68 and 73 were amended to correct various informalities and to further clarify the claims. Claims 80-84 were added to clarify that in some embodiments the control member can comprise a tether that extends along an outer surface of at least a portion of the helically wound wire. Claims 85-90 were added to clarify that in some embodiments at least a portion of the helically wound wire can communicate with the body lumen.

The amendments are fully supported by the figures, specification, and claims as originally filed. In view of the foregoing discussion, Applicant submits that the amendments to the specification and claims do not introduce new matter and entry thereof is respectfully requested.

III. Rejection under 35 U.S.C. § 112

The Examiner rejected claim 73 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action rejects claim 73 for an alleged doubly recitation of the helically wound wire. In view of the amendment made herein to claim 73, in which recitation of the helically wound wire has been removed, Applicant respectfully submits that the rejection has been overcome and should be removed.

IV. Rejection under 35 U.S.C. § 102

The Examiner rejected claims 77 and 78 under 35 U.S.C. § 102(b) as being anticipated by *Green et al.* (US 5674231). Inasmuch as claims 77 and 78 have been cancelled herein, the rejection of those claims is moot and should be withdrawn.

V. Rejection under 35 U.S.C. § 103

Applicant respectfully notes at the outset that in order to establish a *prima facie* case of obviousness, it is the burden of the Examiner to demonstrate that three criteria are met: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP* § 2143.

The Examiner rejected claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75, 77 and 78 under 35 U.S.C. § 103(a) as being unpatentable over *Epstein et al.* (WO 00/06029) in view of *Green et al.* (US 5674231), or *Ginn et al.* (US 6626918) or *Ginn et al.* (6391048). Applicants respectfully traverse this rejection.

Epstein discloses an "Expansile Device for Use in Blood Vessels and Tracts in the Body and Method." *Abstract*. As perhaps best shown in Figures 1 and 2, the Epstein device includes an elongate tubular member 22 having two lumens 26 and 27 extending therethrough from a proximal end 23 to a distal end 24. Tubular member 22 is inserted into a body until the distal end 24 is disposed within a blood vessel through a puncture 106. A closure assembly 32 is disposed at a distal end of the first lumen 26. Closure assembly 32 comprises a coil 34 with an

impervious membrane 36 disposed distal of coil 34. Coil 34 is configured to be elongated while within lumen 26 but to expand to "a generally planar or disk-like configuration" when freed or unconstrained. *See page 5, line 28 to page 6, line 1.*

A wire 41 is attached to the proximal end of coil 34 (i.e., the portion of coil 34 that is farthest away from the distal end 24 of lumen 26) and extends away from the coil toward the proximal end of the first lumen 26. Wire 41 is used to first push coil 34 past the distal end 24 of tubular member 22 (i.e., out of first lumen 26) and then pull coil 34 back into lumen 26. Membrane 36 is attached to tubular member 22 and covers the portion of coil 34 that is pushed out of first lumen 26 so as to prevent fluid from the blood vessel from contacting coil 34 or leaking into lumen 26. When all of coil 34 has been pushed out of first lumen 26, coil 34 then forms the planar or disk-like configuration, with membrane 36 covering coil 34. In this configuration, closure assembly 32 biases against the vessel wall and provides a partial seal against fluid escaping through the wall of the blood vessel through puncture 106. "Such a liquid tight seal is ... necessary ... to prevent the leakage of blood through the puncture 106. This serves to prevent blood from interfering with attempts to safely and permanently occlude and seal the puncture 106 and to prevent inadvertent intravascular deposition of sealant." Page 13, lines 15-25.

Once this partial seal has been formed, a sealant from a syringe 82-87 is passed through the second lumen 27 to the distal end 24 of the tubular member 22, where the sealant exits lumen 27 and surrounds the puncture 106 outside of the vessel. Once the sealant has begun to set up, the coil 34 is retracted back into lumen 26 and the *Epstein* apparatus is removed, leaving nothing but sealant in the body. In this manner, "an excellent biological seal is formed with nothing remaining at the puncture site except for the biological sealant which within a relatively short period of time as for example 1-2 weeks will be absorbed by the body." Page 16, lines 23-27.

The Office Action concedes that Epstein does not teach using a clip, but asserts that "each of the other cited references disclose the use of clips to close vascular punctures, and the two Ginn references disclose that it was known to either supplement a clip closure with a sealant, or that a clip is a known alternative to the use of a sealant in closing vessel puncture wounds." The Office Action then states that it would have been obvious to either add a "clip applying device" to Epstein or replace the sealant in Epstein with a "clip applying device." The Office

Action also states that the wire 41 of Epstein equates to the "claimed tether which contacts an outer surface of the helical wire 38."

Applicant asserts that notwithstanding the assertion in the Office Action that a "clip applying device" can be added to Epstein, it is not apparent at all how this would be done. To add a "clip applying device" would require a major change to the structure of *Epstein*, requiring the addition of structure that could place the clip in position and manipulate the clip once there. Applicant submits that this would require a major redesign of *Epstein*. Simply asserting that a clip applying device can be added to a device is not enough. As such, Applicant submits that the Office Action has not shown the requisite reasonable expectation of success. In addition, as noted above, one of the claimed benefits of *Epstein* is to form "an excellent biological seal ... with nothing remaining at the puncture site except for the biological sealant which within a relatively short period of time as for example 1-2 weeks will be absorbed by the body." This benefit would be lost with the addition of a clip applying device.

Furthermore, Applicant submits that the obviousness rejection is flawed for other reasons. For example, the sole basis for the obviousness rejection of claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75, 77 and 78 is a single allegation made by the Office Action with respect to the cited art. It seems clear from the allegations that, rather than considering each of the claims as written, the Office Action has instead made what appears to be an omnibus-type rejection. This is evidenced by the fact that the Office Action has recited only a single rejection that is represented as being directed to all 47 of the pending claims. In so doing, the Office Action has failed to specifically identify, with any specificity whatsoever, many element(s) of *Epstein* or the other cited art that is/are purported to correspond to the various elements of the pending claims. The Office Action has also failed to even assert, let alone establish, that any of the claimed method steps are taught by the cited art.

Applicant further submits that in the omnibus rejection, the Office Action has rejected various claims based on an erroneously cited claim element. As noted above, the Office Action states that the wire 41 of *Epstein* equates to the "claimed tether which contacts an outer surface of the helical wire 38." Although various claims recite a tether, none of the pending claims recites the limitation that the tether "contacts an outer surface" of anything, let alone the helical wire. Thus, the Office Action has erroneously misstated what is claimed. Instead, claims 12, 22 and 63 (and new claims 80-84) recite "a tether extending along an outer surface of at least the

intermediate portion of the helically wound wire.” Applicant submits that none of the cited art teaches or suggests this claimed limitation. As noted above, the wire 41 of *Epstein* simply attaches to the proximal portion of coil 34 and extends away from coil 34. As such, wire 41 never “extends along an outer surface” of any portion of coil 34. Similarly, none of the cited art teaches this claimed limitation.

In view of the foregoing discussion, Applicant respectfully submits that the Office Action has failed to establish a *prima facie* case of obviousness with respect to claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, and 60-75, at least because the Office Action has failed to establish the existence of a suggestion or motivation to make the purportedly obvious combination, because the Office Action has failed to establish that there is a reasonable expectation of success in combining the references, and because the Office Action has failed to establish that the references, when combined in the purportedly obvious fashion, teach or suggest all the limitations of claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, and 60-75. Accordingly, Applicant respectfully submits that the rejection of claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, and 60-75, should be withdrawn.

VI. Incorrect Attorney Docket No.

Applicant respectfully notes that the Office Action incorrectly references Attorney Docket No. “267/121.” Pursuant to the Change of Attorney Docket Number filed concurrent with this response, the correct docket number for this case is 16497.8.3.2.1. Applicant thus respectfully requests that all applicable USPTO records be updated accordingly, and Applicant further requests that all further communications from the USPTO reference docket number 16497.8.3.2.1.

VII. CONCLUSION

In view of the foregoing, Applicants believe the claims provided in the claim listing are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

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Respectfully submitted,

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